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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,308	03/27/2001	Mathieu Hubertus M. Noteborn	4820US	4047

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

13

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,308

Applicant(s)

Noteborn et al.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 10, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, and 19-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application filed March 27, 2001 claims benefit to foreign application 00201108.8 filed March 27, 2000 with European Patent Office.

Applicants' amendment filed March 10, 2003, paper number 12, has been received and entered. Claims 15, 16, 19, 20 and 21 have been amended. Claims 15, 16, 19, 20 and 21 are pending and currently under examination.

Election/Restriction

Applicant's election with traverse of Group VIII, directed to a method of inducing apoptosis in a cell or in a subject comprising administering a polynucleotide set forth in SEQ ID NO: 1 or SEQ ID NO: 9, in Paper No. 9 was acknowledged. Groups VII and VIII were rejoined because it was Examiner indicated that a search of SEQ ID NO: 9 would identify partial sequences as encompassed by SEQ ID NO: 1, and thus, would not constitute an undue burden. Applicant timely traversed the restriction (election) requirement in Paper No. 9. The requirement is still deemed proper and is therefore made FINAL.

Claims 15, 16 and 19-21 are pending and currently under examination as they are drawn to a method of inducing apoptosis in a cell or a subject by administering either SEQ ID NO: 1 or SEQ ID NO: 9.

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This application contains claims drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The supplemental information disclosure statement filed March 10, 2003, paper number 11, complies with 37 CFR 1.98(a)(2). Specifically, the copies of the two requested references, Zhao *et al.* and Strusberg (wd70d04.x1) have been provided. A copy of the signed and initial PTO-1449 form is included with this action.

Additionally, it is noted that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Upon review of the specification it is noted that a list of references cited in the context of the

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specification are provided on pages 30-34, however, each of the references do not appear to be listed in an IDS. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 15 and 19 are objected to because of the following informalities: both claims 15 and 19 recite administration of "a host cell transformed with an isolated or recombinant nucleic acid of SEQ ID NO 1 or SEQ ID NO 9, and mixtures thereof" and thus, encompass inventions restricted into Groups XI and XII. The elected methods are drawn to delivering specific polynucleotides to cells, not the delivery of host cells. The claims should be amended to reflect the elected invention, deleting embodiments directed to delivering proteins.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 16, and 19-21 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

The amendments to the claims to delete language regarding functional fragments and functional equivalents has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, it is noted that amendments to the claims have obviated the basis of each of the specific rejections previously set forth.

The claims have been amended, and as discussed above in the sections of *Election/Restriction* and *Claims Objections* the embodiment of delivery of a host cell to a subject can be considered to be subject matter encompassed by a non-elected invention. Alternatively, for claims 19-21 as it is directed to inducing apoptosis in a subject, it may be considered a pharmaceutical acceptable carrier for the polynucleotide, as recited in the final line of the method set forth in claim 19. For the sake of compact prosecution, with this interpretation the method is unclear and confusing because the polynucleotide induces apoptosis of the cell in which it is contained, not in any surrounding cells. It is unclear how providing the polynucleotide in the

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context of a pharmaceutical composition of a host cell which at most may undergo apoptosis itself, will provide any form of treatment. Additionally, it is unclear that even if the host cell is removed from the subject and the cell which is removed is subject to the treatment, how or why replacing said cell transfected with the polynucleotide *ex vivo* would provide any form of treatment of any disease in said subject. Again, it is noted that the polynucleotide being delivered will induce apoptosis in cells in which is contained, and thus practicing the method will only provide treatment when the polynucleotide is delivered directly to cells which are subject to treatment. The claims are vague and unclear with respect to practicing the instantly claimed method because the methods require the direct administration of the polynucleotide to the cells to induce apoptosis, and it is unclear how the administration of a host cell containing the polynucleotide would provide any form of treatment of a disease wherein enhanced cell proliferation or decreased cell death is observed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 15 and 15 rejected under 35 U.S.C. 102(b) as being anticipated by Zhuang *et al.*, Oorschot *et al.* and Pietersen *et al.* is withdrawn.

The amendments to the claims to delete the embodiment of functional equivalents and restrict administration to only SEQ ID NOs 1 and 9 has differentiated the instantly claimed invention from that disclosed by Zhuang *et al.*, Oorschot *et al.* and Pietersen *et al.*

Conclusion

The claims are free of the art of record. Claims 15 and 16 are objected to for encompassing a non-elected invention. Claims 29-31 are free of the art of record however they are subject to other rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630